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| **Committee:** | NTB Health and Disability Ethics Committee |
| **Meeting date:** | 1 July 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11:00 - 11:30am |  | *Committee Welcome* |  |  |
| 11:30am - 12:00pm | 2025 FULL 22435 | FLudrocortisone administration in Aneurysmal Subarachnoid Haemorrhage   Acronym: The FLASH Trial  | Dr Chris Hands | Joy / Chris |
| 12:00 -  12:30pm | 2025 FULL 23221 | ENDURA-2: Depemokimab as an Extended treatmeNt DURation biologic in Adults with COPD and type 2 inflammation | Dr James Stanley  | Kate / Amy |
| 12:30 - 1:00pm | 2025 FULL 22077 | Pharmacist-Led Wellness and Wellbeing Service | Professor Jeff Harrison | Kate / John |
| 1:00 - 1:20pm |  | *Break (20 mins)* |  |  |
| 1:20 - 1:50pm | 2025 FULL 20849 | Assessment of an expert system for use with anaesthesia monitors (EDDI) | Dr Matt Kirk-Jones | Kate / Cheng Kai |
| 1:50 - 2:20pm | 2025 FULL 23174 | A Trial to Evaluate Navenibart in Participants with Hereditary Angioedema | Associate Professor Hilary Longhurst | Maakere / Chris |
| 2:20 - 2:50pm | 2025 FULL 23337 | The FLIP-IT trial: Fully automated artificial pancreas in adults with previously above-target type 1 diabetes | Professor Benjamin Wheeler | Kate / Sharon |
| 2:50 - 3:00pm |  | *Break (10 mins)* |  |  |
| 3:00 - 3:30pm | 2025 FULL 23331 | Cultured Corneal Endothelial Cells for Endothelial Failure (Revised) | Dr Sheng Chiong Hong | Maakere / Sharon |
| 3:30 - 4:00pm | 2025 FULL 22510 | Developing a screening test for Biliary Atresia | Dr Stephen Mouat | Kate / Amy |
| 4:00 - 4:30pm | 2025 FULL 23135 | Targeting the Tumour Microbiome to Improve Response to Immunotherapy | Dr Rachel Purcell | Joy / Cheng Kai |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Ms Kate O’Connor  | Lay (Ethical/Moral reasoning) (Chair) | 9/06/2025 | 8/06/2030 | Present |
| Dr Sharon Kletchko | Non-Lay  | 09/06/2025 | 08/06/2029 | Present  |
| Dr Chris Hazlewood | Non-Lay  | 09/06/2025 | 08/06/2030 | Present |
| Ms Alice McCarthy | Lay (the Law) | 22/12/2021 | 22/12/2024 | Apology |
| Dr Cheng Kai Jin | Non-Lay  | 09/06/2025 | 08/06/2028 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Dr Joy Panoho | Lay | 03/03/2025 | 02/02/2030 | Present |
| Dr Amy Chan | Non-Lay | 09/06/2025 | 13/07/2030 | Present |
| Associate Professor John Pearson | Non-Lay | 09/06/2025 | 08/06/2029 | Present |

## Welcome

The Chair opened the meeting at 11:00am and welcomed Committee members, noting that apologies had been received from Alice Mcarthy

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 3 June 2025 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **FULL 22435** |
|   | Title:  | A prospective, blinded, randomised clinical trial of fludrocortisone compared with placebo in critically ill patients presenting with aneurysmal subarachnoid haemorrhage |
|   | Principal Investigator:  | Dr Chris Hands |
|   | Sponsor:  | The George Institute for Global Health |
|   | Clock Start Date:  | 19 June 2025 |

Dr Chris Hands was present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee discussed the non-consent enrolment of critically ill participants. It was resolved that enrolling without consent was justified under Right 7.4 of the Code of Health and Disability Services Consumers' Rights where enrolment in the study would be in the best interests of the participants as they will receive additional monitoring and follow-up referrals beyond standard care. Participants who recover the capacity to consent will be able to provide consent for the continued use of their data.
2. The Researchers clarified that the investigational drug has a well-characterised safety profile from other uses. The principal risk identified was elevated sodium levels, which is easily managed by stopping the drug.
3. The Researchers clarified that, while the global study protocol included collecting and shipping biological samples overseas, this would not be included in the New Zealand arm of the study to comply with New Zealand law and ethical requirements.
4. Researchers clarified that participants would likely be on the ward when giving consent to continue to be in the study. Research coordinators will be approaching participants for this continued consent.
5. Researchers confirmed that records of doctors signing off on best interest will be kept with enrolment paperwork.
6. The Researchers confirmed that the screening for enrolment and eligibility occur in parallel with ongoing clinical care, so there is no delay or withholding of necessary treatment for participants.
7. The Researchers clarified that ethnicity would be collected per Stats New Zealand standards
8. The Researchers clarified that only severe organ failure would exclude a patient from participation in the study and mild comorbidities would not. This would be a clinical judgement made at the time of consent.
9. The Researchers clarified that, should a participant receive a high dose for treatment of an allergy while in the ICU this would be noted and flagged on the report for the study, but would hope to keep the patient’s data in the study.
10. The Researchers clarified that study drugs are supplied in standard dosing packs by the study group and that the research team have experience with blinded studies and will have one person allocated to blinded role and another from unblinded role when preparing study drugs.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee noted inaccuracies in the submitted documents and requested that all study documents be revised to ensure the project title, site references, and other details are correct and specific to this trial.
2. The Committee noted that the study was described as Kaupapa Māori, however, this study does not meet the criteria for kaupapa Māori research (i.e. by Māori, for Māori, with Māori). As such, the Committee requested that researchers note for any future that the research methodology should be accurately described without misrepresenting it as kaupapa Māori.
3. The Committee requested that a clearer, more robust response plan for any participant showing severe distress or suicidal thoughts be developed. This should include immediate steps (such as ensuring the person has access to emergency support or contacting crisis services if necessary) and not solely a reliance on GP notification.
4. The Committee requested that the Data Management Plan reference to unspecified future use of collected data be removed as this is not permitted in non-consenting studies.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please adjust the Participant Information Sheet to correct the tone and tense to address the participant directly, and describe any procedures that have already occurred in past tense
2. Please remove yes/no check boxes from the consent form. Instead, use a single signature line to indicate consent
3. Please ensure that the PIS has the correct study title.

The Committee requested the following changes to the RWF consultation sheet.

1. Please revise the RWF document to address family members, as it is currently written solely for patient consent. This document should also be revised to ensure it is clear that it is looking for an ascertainment of wishes from family members as opposed to giving consent.
2. Please do not refer to the study intervention as a ‘treatment’ as this is still research
3. Please identify the Sponsor in the header
4. Please revise consent statements for context

**Decision**

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Joy Panoho and Dr Chris Hazlewood.

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| **2**   | **Ethics ref:**   | **FULL 23221** |
|   | Title:  | 222725: A randomized, double-blind, placebo-controlled, parallel-group, multicenter study of the efficacy and safety of depemokimab in adult participants with COPD with Type 2 inflammation |
|   | Principal Investigator:  | Dr James Stanley |
|   | Sponsor:  | GlaxoSmithKline Research & Development Limited |
|   | Clock Start Date:  | 19 June 2025 |

James Stanley and Charlene Botha were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Researchers confirmed that the study drug has a longer half-life and can support dosing every 26 weeks.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee requested that the advertisement documents be revised to remove emotive language such as “fear of COPD flare-ups keeping you close to home”. The documents should also be revised to be more appropriate to the New Zealand context and reference to there being no requirement of insurance can be removed.
2. The Committee requested a clear plan to manage cases where investigators may also be involved in participants’ clinical care, so patients don’t feel any pressure to join the study from their own doctors.
3. The Committee noted that different documents indicated different data and sample retention periods and requested that information describing retention periods for study data and biological samples be clarified across all documents. If certain data are kept longer, explain the reason to participants.
4. The Committee requested that a contact phone number be added to the appointment reminder card for quick reference.
5. The Committee noted that the DMP references saliva and requested that this be clarified as it is not explicitly mentioned elsewhere in study documentation.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please explain in more detail what is meant by ‘some tests may be uncomfortable’, clarify what tests could be uncomfortable and what can be done to alleviate any side effects or adverse events.
2. Please add a brief explanation of “Type 2 inflammation” in the PIS.
3. Please revise PIS for length and remove repeated information where possible.
4. Please remove references to ‘race’.
5. Please revise the use of the word ‘treatment’, as this is still research (therapy/procedure) being carried out.
6. Please use gender neutral language.
7. Please revise section indicating that the study doctor should be the first contact in the event of chest pain, this should be the Public Hospital Emergency Department.
8. Please provide information pertaining to SCOUT in the PIS for sites to use where necessary.
9. Please provide the reimbursement details in the PIS once finalised so participants are aware of what support is available for transportation.
10. Please remove the option that allows participants to request their data be removed if they withdraw from the study as mandatory data retention is indicated in the protocol and Data Management Plan.
11. Please revise statement “discarding biohazard waste” in the consent form, “disposal of study samples” could be used.

**Decision**

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O’Connor and Dr Amy Chan.

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| **3**   | **Ethics ref:**   | **FULL 22077** |
|   | Title:  | Pharmacist-Led Wellness and Wellbeing Service for LTC Patients with Subthreshold Depression/Anxiety |
|   | Principal Investigator:  | Professor Jeff Harrison |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 19 June 2025 |

Patrick Cabasag was present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

Amy Chan declared a potential conflict of interest and the Committee decided to have the member sit out on discussion regarding this application.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Researcher confirmed that engagement with Māori stakeholders has taken place, and a Māori-focused workshop was conducted to ensure the service is culturally safe.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee identified that the current scope of the project is very large and would benefit from being restructured into manageable stages. The Committee proposed that the study be separated into component phased projects. A phase focusing solely on recruiting pharmacies to confirm they will have the resources and time to participate in the later stages of the study. Contact with head offices seeking organisational consent and permission should be sought. A phase focused on training pharmacists and how that would work best can also be done as a separate project (potentially in tandem with the first phase). Then, a project that will address the wellness service with patients themselves. This phased approach will make the study more feasible and allow lessons from the first and second phases to inform the patient facing phase *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.1).*
2. The Committee recommended that future projects adopt a secure electronic data capture system (such as REDCap) for collecting participant information and questionnaire data especially in a multicentre study. This will ensure consistency across sites, reduce the risk of lost or misplaced data, and streamline data analysis (as all entries are centralised). The Committee highlighted that most universities provide access to such platforms and that electronic data capture is now considered best practice for multi-site studies. The Data Management Plan for each phase can be updated with the use of an electronic data capture system and can make use of university governance plans.
3. The Committee noted that the design for this feasibility study should be adapted to ask more detailed questions to less people per pharmacy, while increasing the number of pharmacies participating in the feasibility study. The Committee noted that qualitative data can also be collected at this stage in a study and provide valuable insights.
4. The Committee requested that the study adopt a passive recruitment approach for people in the pharmacy where flyers, posters, or electronic advertisements in the pharmacy are utilised to invite patients to learn about the study as opposed to directly approaching people in pharmacies. Interested individuals can then contact the researcher or speak to pharmacy staff privately, rather than being solicited on the spot.
5. The Committee noted that a protocol paper outlining the aims of the overall project can be written and referred to as each of the phases commence. This, along with the completion of each phase will build upon the knowledge base and information to reference when applying for each subsequent phase of the overall project.
6. The Committee highlighted that aspects of this project can be carried out prior to HDEC approval, such as reaching out to pharmacies to ascertain interest.
7. The Committee requested that a comprehensive training outline for pharmacists be provided when application for this phase takes place. The training should go beyond just how to administer the wellness intervention, it should also include how to obtain informed consent, maintain confidentiality, manage data securely, and handle any participant questions or issues during the study.
8. The Committee noted that terms like “wellness and wellbeing” were being used in the advertising materials in place of “subthreshold anxiety and depression” and requested that this be replaced with clear descriptions of what participants are being screened or helped with. Pharmacies will be able to assist in describing what will work best for their customers.
9. The Committee noted that much of the DMP has come directly from the template and needs to be customised to this project. For example, section 8.5 of the DMP has very broad unspecified future use of data information which is not appropriate at this stage of the study.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please refer to the HDEC Participant Information Sheet using the template to ensure completeness and clarity.
2. Please include a simple flowchart or timeline of the study activities in the PIS. This visual aid could outline steps such as initial contact, the wellness consultation at the pharmacy, any follow-up interactions or questionnaires.
3. Please consider revising the current PIS to be more concise and reader friendly, the current document has a sombre tone which can be made more positive or neutral while still being honest about any risks or commitments.

**Decision**

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above.

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| **4**   | **Ethics ref:**   | **FULL 20849** |
|   | Title:  | Assessment of software for the Early Detection of Diagnostic Information (EDDI) during anaesthesia |
|   | Principal Investigator:  | Dr Matt Kirk-Jones |
|   | Sponsor:  | Te Whatu Ora Waitematā |
|   | Clock Start Date:  | 19 June 2025 |

Michael Harrison was present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Researcher clarified that this anaesthetic monitoring system is a long-term academic endeavour, not driven by personal profit or commercial reasons. The Committee was satisfied that this is not principally commercially driven and that ACC coverage for participants would not be compromised.
2. The Committee queried the frequency of alerts generated by the EDDI system and potential impact on anaesthesia staff. The researcher explained that alerts would occur on average under 2.5 times per hour with approximately 0.7–1.2 diagnostic alerts per hour, and the same frequency for system alerts
3. The Researcher confirmed that the possible two analysis methods for this study are outlined in the protocol documents and highlighted that the preference would be to implement both into the analysis plan. The two methods outlined analysis for correlating alerts with patient state, where one analysis plan has the advantage of assessing true negatives, while the other looks for total positive events but does not assess true negatives.
4. The Researcher noted that providing each participant with their detailed information would be impractical and of little meaning to a layperson. Instead, participants will be offered a plain-language summary of the overall study results at the conclusion of the trial.
5. The Researcher clarified that the anaesthetic data collected by the system contain no direct personal identifiers aside from date/time stamps and a secure, hospital-provided laptop will be used for data capture to ensure no patient information is exposed
6. The Researcher clarified that the safer sleep record was noted to serve as a supplementary source of information (actions and treatments administered) for recording information which can be used along with diagnostic information.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee indicated that a waiver of written consent would not be approved, and that written informed consent must be obtained. The Committee noted that the participation and consent discussion can occur during the face-to-face conversation between the patient and their anaesthetist and that obtaining a signature in this situation would not be burdensome.
2. The Committee requested that participants are given study information before the day of the procedure as they must have sufficient time to consider involvement and to discuss participation with family. The Committee acknowledged that this could impact logistics around operating theatres as raised by the Researcher.
3. The Committee recognised that the amount of data collected from 200 recruited participants would likely result in a considerable amount of data for analysis, however, requested that the Researcher obtain a peer-review by a biostatistician for sample size to ensure the data collected will be meaningful and the analysis robust.
4. The Committee requested that the Data Management Plan clarify that all research data will remain stored in New Zealand and no identifiable data will be sent overseas.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please remove the reference to ‘sponsor’ if referring to Te Whatu Ora, Waitematā, at North Shore Hospital as the locality.
2. Please provide contact details for the co-ordinating investigator

**Decision**

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O’Connor and Dr Cheng Kai Jin.

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| **5**   | **Ethics ref:**   | **FULL 23174** |
|   | Title:  | A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Navenibart in Participants with Hereditary Angioedema |
|   | Principal Investigator:  | Associate Professor Hillary Longhurst |
|   | Sponsor:  | Astria Therapeutics, Inc. |
|   | Clock Start Date:  | 19 June 2025 |

Dr Hilary Longhurst and Keri-Anne Cowdrey was present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Researchers agreed with the Committee that the advertising materials would not be used in New Zealand as the Committee considered that the sponsor-provided recruitment advertisements were overly persuasive. Additionally, the Researchers clarified that the majority of participants are recruited via word of mouth.
2. The Researchers confirmed that participants aged 12–17 would not be randomised to a placebo group in this trial, as it reduces burden and risk for adolescent participants. This design choice addressed concerns about exposing younger participants to a placebo and thus potentially withholding effective therapy during the trial.
3. The Committee observed that the researchers had appropriately handled consent for minors in line with New Zealand guidelines. Specifically, 16- and 17-year-old participants can consent for themselves, while those under 16 require parental consent with assent.
4. The Researchers confirmed that an application for a long-term extension would be submitted to HDEC as a new application.
5. The Researchers clarified that if a potential participant were to approach them about participating in the study while on another medication for the condition the nuance of the risks and potential benefits of the study for each individual would be addressed and discussed with the potential participant during the screening stage.
6. The Researchers confirmed that all participants of childbearing potential are asked to undergo at home pregnancy testing, for which only verbal confirmation is required.
7. The Researchers clarified that avoidance of medications outlined in the protocol as prohibited medications is already standard medical advice for all HAE patients, outside the trial context. The Committee agreed that that participants should already be aware of these precautions and so this information was not required in the PIS

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please update emergency contact instructions to prioritise calling 111 before contacting the study doctor, for any cases of suspected anaphylaxis. This action is required on the PIS and on the Patient information card.
2. Please ensure that GP notification is compulsory
3. Please revise references to ‘treatment’ when referring to an unapproved medicine.
4. Please remove references to ‘race’ as it is not suitable to the New Zealand context
5. Please explicitly state in the PIS/consent forms that participants under 16 years of age must have a parent or guardian provide consent (in addition to the child’s assent), whereas those aged 16–17 may consent on their own. Additionally, a note should be included that if a participant enrolled as a child turns 16 during the study, they will be required to sign the adult consent form to continue in the trial.
6. Please review all Māori words in documentation including macron in ‘whānau’.
7. Please ensure the Participant information sheets, and assent forms mention the requirement for pregnancy tests and advise on contraceptive measures for participants in an age-appropriate manner
8. Please insert contact information for the Māori cultural advisors into the PIS.
9. Please ensure that it is clear that HDECs approve only ethical aspects of the study.
10. Please ensure that the amount of koha is specified in the PIS.

**Decision**

This application was *approved* by consensus, subject to the following non-standard conditions:

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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| **6**   | **Ethics ref:**   | **FULL 23337** |
|   | Title:  | Closing the loop with the FLIP-IT trial – Fully automated insulin delivery and patch pumps in adults with type 1 diabetes and above-target glycaemia |
|   | Principal Investigator:  | Professor Benjamin Wheeler |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 19 June 2025 |

Ben Wheeler and Alisa Boucsein were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee were satisfied, after clarification from the researchers in this resubmission, that this study is investigator initiated and not for commercial benefit.
2. The Committee queried the comparison to the new device to various other devices and the potential for this to introduce too many variables, the Researchers explained that the aims of this control group is isolate the effect of the new closed-loop algorithm versus standard care, noting that all participants, including controls, receive the same additional dietitian support.
3. The Researchers confirmed that they are not looking to recruit children in this study.
4. The Committee noted that the submitted Māori consultation letter was dated and referred to a different study. The Researchers explained that they have ongoing cultural engagement, including a Māori advisory group, a Pacific advisory group, and in-person consultation with Ngāi Tahu representatives for the current study.
5. The Committee clarified that the provisional approval for this application applies to phase 1 and 2 of the study and does not include an approval for phase 3 of this study.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee noted that one phase of the study looks to use an approved medicine but in an off-label use, and another phase proposes to use an unapproved medication in New Zealand. The Committee requested that the researchers notify SCOTT of any off-label use of approved medications and obtain SCOTT review/approval for the use of any unapproved medicine. As the unapproved medicine is planned to be used in the later phases of the study the Committee decided that the review of this application will consider phase one and two of this study separately from phase three. Noting that what is currently phase three of the study can be submitted as a post approval amendment once it has approval and is ready to begin.
2. The Committee requested that the protocol appendix be revised for any references to systems not included in this study.
3. The Committee noted that principles of Māori data sovereignty are respected for data held in New Zealand, they cannot be applied to data stored in the cloud.
4. The Committee requested additional safety monitoring in the form of a depression screening tool be included for the third phase of the study (for its application). This screening should be done at baseline and during the intervention, to promptly identify any significant concerns. If a participant’s screening indicates high risk, the study team must follow up and refer the individual for appropriate mental health care. Plans for this monitoring and referral process should be outlined in the protocol and communicated to participants in the consent materials for that phase.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please update the PIS to list medications involved in the study and state that their use in this study is off label.
2. Please revise the PIS/CF to reflect the phased approach. The overall study design (all three phases) can be outlined using a diagram or overview but a specific information sheet and consent form for each distinct phase should be utilised (phase one and two could potentially be incorporated into one document). Indicate that after completing the initial 13-week phase, participants may be invited to join the next phase, and that new information and consent will be sought at that point.
3. Please update the contraception requirements section and remove mention of contraceptive methods not applicable in NZ.
4. Please clarify in the costs section for those in the control group that their current insulin pump or therapy and supplies will continue to be funded as usual, so they will not incur costs for standard care.
5. Please clearly explain that continuous glucose monitor data will be stored in a cloud database overseas in a de-identified form. State that identifiable research data, such as interview responses and health records collected for the study, will be stored securely in New Zealand.
6. Please include a statement in the phase 3 information sheet that participants will be asked to complete brief mood/depression questionnaires during the study. Explain this is to monitor safety due to the medication’s known side effect profile, and that if concerning symptoms are identified, the study team will assist in arranging appropriate support

**Decision**

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O’Connor and Dr Sharon Kletchko.

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| **7**   | **Ethics ref:**   | **FULL 23331** |
|   | Title:  | Cultured Corneal Endothelial Cells for Endothelial Failure |
|   | Principal Investigator:  | Dr Sheng Chiong |
|   | Sponsor:  | oDocs Eye Care Ltd |
|   | Clock Start Date:  | 19 June 2025 |

Dr Sheng Chiong, George Dias, and Renoh Chalakkal were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Researchers confirmed that all imported human tissue is handled under an appropriate Material Transfer Agreement (MTA) and processed in a certified PC-2 laboratory as required for human tissue samples. These measures are in place to meet required biosafety standards.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee noted that application documents were inconsistent with the actual study activities, containing details relevant only to a future clinical trial phase. As such the Committee requested that the Researchers revise the protocol and Data and Tissue Management Plan to focus solely on the current laboratory phase. Remove or correct any references to recruiting participants or other clinical procedures that are not applicable at this stage *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8;12.15a, 14.16&14.17)*.
2. The Committee requested that the original donor information sheet/consent form from study associated with donation of tissue from Australia be provided. This will allow the committee to verify that the tissue’s intended use in this study is consistent with the consent given by the donors’ next of kin *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 14.22).*
3. The Committee noted that the cultural consultation and Māori engagement appears to be overstated and that equitable claims are not necessarily applicable for the current lab-only phase of the study. Additionally, the Committee requested that the “kaupapa Māori methodology” references be removed as this is this study does not exclusively involve Māori participants nor is it a Māori-led design *(National Ethical Standards for Health and Disability Research and Quality Improvement, Kaupapa Māori research page 43).*
4. The Committee requested that the researchers provide letters of support or consultation records from the named iwi or other Māori advisory groups specifically for this phase of the project. The Committee requested that substantial evidence of Māori consultation is provided if it is claimed, especially given the cultural significance of human tissue use *(National Ethical Standards for Health and Disability Research and Quality Improvement, Chapter 3;14).*
5. The Committee requested that the Research team formulate a plan to address cultural and spiritual concerns related to the use of donated tissue. This will involve continued engagement with Māori and Pacific advisors to ensure that future phases, especially any involving tissue transplantation into patients respect cultural and spiritual values and beliefs about human tissue and organ donation *(National Ethical Standards for Health and Disability Research and Quality Improvement, Chapter 3;14)*.

**Decision**

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above.

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| **8**   | **Ethics ref:**   | **FULL 22510** |
|   | Title:  | Development of a screening test utilising new-born screening samples for Biliary Atresia |
|   | Principal Investigator:  | Dr Stephen Mouat |
|   | Sponsor:  | Starship Children's Health Te Toka Tumai |
|   | Clock Start Date:  | 19 June 2025 |

Stephen Mouat was present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Researcher confirmed that the use of Guthrie card samples is covered by existing parental consent and that the study aims to test how different environments and exposures could affect the samples, using second control samples that will be known to provide a signal.
2. The Researchers clarified that a nurse specialist will make the initial approach to families about the research instead of the treating doctor approaching their own patients to join the study. This will reduce the potential for undue influence in recruiting patients.
3. The Committee acknowledge that the evidence of grant approval shows evidence of consultation, however, note that locality authorisation may require further consultation.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee requested that the data and tissue management plan be updated to remove any irrelevant template content and include the appropriate governance details. The University of Auckland’s research data/tissue governance policies can be used. Ensure that it is clear where tissues and research data will be stored for the long term, whether in the hospital or at the university (for both tissues and data).
2. The Committee suggested that a koha to participants, such as a coffee voucher for the parents or a small gift for the baby could be provided if appropriate.
3. The Committee requested that a secondary person be designated who can securely hold the data key or access code. Having a backup custodian for the identifying information ensures continuity in data access and security in case the primary investigator is not available when data needs to be accessed or decoded.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please remove reference to the control group as “well babies.” the treatment and control groups can be referred to as infants with and without liver disease.
2. Please clarify the tissue and data storage plans in the PIS. Outline the various possibilities for storage, whether a sample will be kept for 15 years, used up completely, or if samples can be returned and under what circumstances this may occur. Explain that data will be stored for 26 years, as this will be in line with the requirement that data is held for 10 years after the youngest participant turns 16.
3. Please define technical terms for a lay audience.

**Decision**

This application was *approved* by consensus, subject to the following non-standard conditions:

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* please update the data management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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| **9**   | **Ethics ref:**   | **FULL 23135** |
|   | Title:  | Novel Approaches for Targeting the Tumour Microbiome to Improve Response to Immunotherapies in Colorectal Cancer |
|   | Principal Investigator:  | Dr Rachel Purcell |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 19 June 2025 |

Researchers were not present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

John Pearson declared a potential conflict of interest and the Committee decided to have the member abstain from discussion regarding decision for this application.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee requested that the researchers obtain sponsor sign off research and enterprise as per the Otago policy.
2. The Committee noted that the application’s Data and Tissue Management Plan (DTMP) included reference to future unspecified research without a specific consent for that use. As such, the Committee requested that the DTMP remove any reference to future unspecified research.
3. The Committee noted that the submission indicates that this project follows Kaupapa Māori methodology, yet little detail has been provided. The Committee requested that the researchers clarify if this project truly follows Kaupapa Māori methodology framework, or if cultural consultation has been interpreted as informing this project as Kaupapa Māori. Regardless, further detail is required addressing all of the cultural considerations and actions that are being undertaken in this study. The hui must be clearly described in terms of their purpose, whether they are intended for recruitment, consultation, or both. The organisation of hui should be detailed, including who will be involved, when they will occur, and how they will be coordinated. Māori participants should be informed about the research prior to their arrival at the pre-surgical assessment and any documentation related to this needs to be uploaded.
4. The Committee requested clarification on whether samples will be sent overseas, as mentioned in the DTMP. If this is the case, please ensure it is explicitly stated in the PIS.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please revise PIS to ensure it is clear that samples are coded or deidentified, not "anonymised".
2. Please distinguish collection, access, storage (10 years) and destruction of identifiable and coded samples and data as per the HDEC template.
3. Please ensure the description of “creating models” in the context of organoids is clearly explained in the PIS. Clarify that this refers to growing these organoids to mimic (model) organ behaviour. Inclusion of a diagram could assist participant understanding of these organoids.
4. Please clarify linkage to health records and explain what limits are set in place for the use of this data, outline if this extends to future use or linkage.
5. Please ensure there is an option to receive a summary report on the Consent Form.
6. Please provide the option for opting in to the mailing list to receive general updates on studies that made use of this particular tissue cohort on the consent form.
7. Please ensure participants are well informed as to what “healthy controls” samples are, clarify whether these samples will be collected from the participant’s own procedure (that may also have polyp tissue collected) for comparison, or from separate healthy volunteers.
8. Please ensure the PIS addresses the participants that accounts for any post operative pathways they may follow. A PIS presented to a patient waiting for a colonoscopy indicating that the study is interested in colorectal cancer can be confronting. Wording in the PIS can be revised to include ‘healthy looking tissues’ in addition to references to tumours and polyps.
9. Please clarify the pathway of collected tissue samples after the procedure, outlining that only samples that are not used up in diagnostic testing will be used for the study. A diagram or flow chart may assist in clarifying this pathway for participants.
10. Please revise the PIS for overuse of the term ‘tumour’ as not all participants will have tumours.
11. Please specify the timeframe and limitations of withdrawal, outlining that participants may be able to withdraw samples until they are aggregated and analysed.
12. Please include an option for a karakia when disposing of tissue.
13. Please include a checkbox on the consent form for participants who agree to be contacted with general study updates.
14. Please remove the option for notification of the participant’s GP of abnormal results from the consent form. Outline that that this study will not yield any incidental clinical results that require GP notification as any important findings will be discovered and handled through colonoscopy standard care procedures.
15. Please clarify whether participant’s de-identified data and tissue will be made available to other researchers and if the data will be used to form larger datasets. If so, this information will need to be reflected within the patient consent forms.

**Decision**

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
4. Please update the data and tissue management plan, taking into account the feedback provided by the Committee (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Joy Panoho and Dr Cheng Kai Jin.

## General business

1. The Chair reminded the Committee of the date and time of its next scheduled meeting:

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| **Meeting date:** | 5 August 2025 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 4:30pm.